

I. Specific Reference to a Prior Application and Specification Informalities

1. The office action states that the application must contain a specific reference to any prior application. Such a cross reference to prior (parent) applications was added to the first page of the specification of this application by page 6 of the preliminary amendment filed in this application on July 28, 2003.
2. Please amend the second "D" on page 34, lines 29 of the application to "E", as shown by the attached amended page 34 of the specification..
3. The Abstract on page 42 of the application fully complies with MPEP 608.01(b). There is no requirement to have an application number in the Abstract.
4. The 42 page specification has page numbers located at the bottom center of each page after page one.

II. Section 112(2) Rejection

Claim 21 was rejected under 35 U.S.C. section 112, second paragraph.

Applicants hereby cancel claim 21 without prejudice to further prosecution at a later date.

As claim 21 has been cancelled the rejection of claim 21 should be withdrawn.

### **III. Double Patenting Rejection**

Claims 19 and 20 were provisionally rejected under 35 U.S.C. section 101 over claim 19 and 20 of co-pending application number 10/114,740.

Claim 21 was not rejected. Claims 19 and 20 have been amended to incorporate the limitations of claim 21. Hence the rejection should be withdrawn.

#### **IV. Section 102(e) Rejection over Mukherjee**

Claim 19-23 were rejected under 35 U.S.C. section 102(e) as being anticipated by Mukherjee. Respectfully, the rejection is in error and should be withdrawn.

1. The priority date of this application is **August 10, 1999** (to parent application number 09/371,354) as set forth by both the preliminary amendment filed July 28, 2003 and by the filing receipt in this application. It can be noted that page 26, lines 25-26 of application number 09/371,354 states "Other mechanisms for local intracardiac neurotoxin delivery include eluting stents...". As set forth on page 12, lines 6-7 of application number 09/371,354, botulinum toxin is a neurotoxin.

Mukherjee was published in **2000**. Thus, the Mukherjee publication is not prior art with regard to the claim in this application and the rejection over Mukherjee should therefore be withdrawn.

2. Furthermore, Mukherjee teaches use of expandable metal stents "EMS") in conjunction with injection of a botulinum toxin to treat achalasia. As explained on page 2185 right hand side column of Mukherjee each EMS consisted of a stainless steel wire mesh coated with a polyethylene film. There is no teaching or suggestion in Mukherjee to coat, attach or embed any drug (including any botulinum toxin) in or on any stent.

Table 1 on page 2186 of Mukherjee merely indicates that separate Botox (a botulinum toxin type A) injections were made in conjunction with use of a stent - as explained on page 2186, left hand side column of Mukherjee, in the third sentence of the section entitled "Methods", and on page 2186, right hand side column of Mukherjee, in the last sentence of the section entitled "Eligibility Criteria".

Thus, because Mukherjee does not teach or suggest a stent with a botulinum toxin attached or imbedded in or on the stent (the claimed subject matter) the rejection should be withdrawn.

V. Section 102e) Rejection over Unger

Claim 19-24 were rejected under 35 U.S.C. section 102(e) as being anticipated by Unger. Respectfully, the rejection is in error and should be withdrawn.

1. The priority date of this application is **August 10, 1999** (to parent application number 09/371,354) as set forth by both the preliminary amendment filed July 28, 2003 and by the filing receipt in this application. It can be noted that page 26, lines 25-26 of parent application number 09/371,354 states "Other mechanisms for local intracardiac neurotoxin delivery include eluting stents...". And as set forth on page 12, lines 6-7 of application number 09/371,354, botulinum toxin is a neurotoxin.

Unger was filed **May 1, 2000**. Thus, the Unger patent is not prior art with regard to the claim in this application and the rejection over Unger should therefore be withdrawn.

## VI. Conclusion

All issues raised by the Office Action have been addressed. Reconsideration, reexamination and allowance of claims 19-20 and 22-24 is requested.

Respectfully Submitted,

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### CERTIFICATE OF EXPRESS MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that the Response to Office Action and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date July 13, 2004 in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV 193 718 770 US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Adriane Giberson  
Name of person mailing paper

  
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Signature of person mailing paper

Date: July 13, 2004